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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WECKER, JENNIFER	

ART UNIT	PAPER NUMBER
1772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,106	SCHWERTNER ET AL.	
	Examiner	Art Unit	
	JENNIFER WECKER	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. It is acknowledged that claims 1, 10 and 24-25 have been amended.

2. It is acknowledged that claim 4 has been cancelled.

3. Therefore claims 1-3 and 5-25 are pending prosecution in this application.

4. Objection to claims 24-25 has been withdrawn, in view of the amendment.

5. In view of these amendments, a new grounds of rejection is presented below.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding Claims 1 and 10, it is unclear how the surfaces of the device are represented as symbols, does this mean that each surface simply contains a symbol or part of a symbol or is the surface actually a symbol? In addition, it is unclear in a different manner from what that these surfaces are arranged.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-3 and 5-14 and 16-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Brown III et al. (U.S. Patent No. 5,160, 701) in view of Blatt et al. (U.S. PGPub 2005/0249633).

12. Regarding Claim 1, Brown III. et al. teach a device to detect molecules or molecules classes or molecule mixtures (see abstract and Col. 1 lines 15-26), characterized in that

a) at least two surfaces with immobilized molecules or molecule classes are provided on a panel of the device (referred to as matrix 12), whereby one surface is employed for control or standardization purposes (referred to as surface 12b), and the other serves to detect an analyte (referred to as sample-contacting surface (reaction site) 12a) (see Col. 6 lines 21-30), whereby

b) the two surfaces are structured in such a manner that they come into contact at the same point in time with an entire sample from which molecules or molecule classes or molecule mixtures are to be tested for (see Col. 3 lines 15-28 and Figure 1),

c) whereby both surfaces are structured and arranged with respect to each other in such a manner that they are evaluated jointly, thereby forming a graphic arrangement that can be read out visually (See Col. 10 line 64 - Col. 11 lines 67 and Figures 3C and 6A-C), and

d) the surfaces are represented by one or many symbols linearly or in a matrix arranged in a different manner. See Figure 1 and Col. 10 line 64 – Col. 11 line 67.

13. Brown III et al. do not teach that the surfaces are arranged in a matrix or coordinate system.

14. Blatt et al. teach a cartridge for detecting and/or quantifying at least two different analytes using at least two different techniques, in a single sample. The cartridge 200 comprises two or more test sites 208 which are typically embedded in or adjacent to the sample distribution layer 204 and which may be arranged in a coordinate system. See [0081] and Figure 2A. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to arrange the surfaces of the Brown invention in this manner so that at least two different analytes could be simultaneously analyzed using at least two different techniques.

15. Regarding Claim 2, Brown III. et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are in a planar and/or spatial arrangement with respect to each other. See Figure 1, Col.3 lines 15-26, and Col. 6 lines 21-30.

16. Regarding Claim 3, Brown III. et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that the sample from which the

analyte or analytes is to be tested for is present in liquid, solid or gaseous form or else in physical intermediate states or combinations thereof. See Col. 3 lines 1 – 26 and Col. 6 lines 44-59.

17. Regarding Claim 5, Brown III et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that the immobilized molecules or molecule classes are visually evaluated together by means of a detection reaction without additional technical aids, whereby the various surfaces appear colored, black, gray, or are tinted in a mixture of colors and/or shades of gray. See Col. 7 lines 34 -43.

18. Regarding Claim 6, Brown III et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that it is configured as a vessel having one or more openings (referred to as fluid chamber 17). See Col. 6 lines 44-50 and Figure 3A.

19. Regarding Claim 7, Brown III et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are located inside the vessel (referred to as fluid chamber 17) or else on or more surfaces are located on the vessel wall. See Figure 3A.

20. Regarding Claim 8, Brown III et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are rendered visible as symbols, "—" for negative and "+" for positive, or a circle for negative and a circle with a dot or dots in it for positive. See Col. 11 lines 49 – 67, Col. 17 lines 37 – 60, and Figures 3B and 3C.

21. Regarding Claim 9, Brown III et al. teach a device to detect molecules or molecule classes or molecule mixtures characterized in that the immobilized molecules or molecule classes and/or mixtures are selected from a group consisting of antibodies, antigens, DNA, RNA, enzymes, substrates, receptors, ligands, or combinations thereof. See abstract.

22. Regarding Claim 10, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures comprising

a) establishing contact between a sample from which molecules or molecule classes or molecule mixtures are to be tested for with the panel of a device in such a manner that they come into contact at the same point in time with the entire sample from which molecules or molecule classes or molecule mixtures are to be tested for (see Col. 3 lines 50-60), whereby at least two surfaces on the panel of the device are provided with immobilized molecules or molecule classes and/or mixtures in such a way that one surface is employed for control or standardization purposes (referred to as surface 12b), and the other serves to detect an analyte (referred to as sample-contacting surface 12a), and whereby the two surfaces are structured and arranged with respect to each other in such a manner that they are evaluated together, and that they form a graphic arrangement that can be read out visually, and the surfaces are represented by one or more symbols linearly or in a matrix arranged in a different manner (see Col. 10 line 64 - Col. 11 lines 67 and Figures 1,3C and 6A-C), and

b) read-out and evaluation of the surfaces. See Col. 4 lines 6-12.

23. Brown III et al. do not teach that the surfaces are arranged in a matrix or coordinate system.

24. Blatt et al. teach a cartridge for detecting and/or quantifying at least two different analytes using at least two different techniques, in a single sample. The cartridge 200 comprises two or more test sites 208 which are typically embedded in or adjacent to the sample distribution layer 204 and which may be arranged in a coordinate system. See [0081] and Figure 2A. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to arrange the surfaces of the Brown invention in this manner so that at least two different analytes could be simultaneously analyzed using at least two different techniques.

25. Regarding Claim 11, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are read out in a planar and/or spatial manner. See Figure 1, Col.3 lines 15-26, and Col. 6 lines 21-30.

26. Regarding Claim 12, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the various detection surfaces appear colored, black or gray, or are tinted in a mixture of colors and/or shades of gray. See Col. 7 lines 34 -43.

27. Regarding Claim 13, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are read out in one or many symbols linearly or in a matrix arranged in a different manner. See Figure 1 and Col. 10 line 64 – Col. 11 line 67.

28. Regarding Claim 14, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are rendered visible as symbols, "-" for negative and "+" for positive, or a circle for negative and a circle with a dot or dots in it for positive. See Col. 11 lines 49 – 67, Col. 17 lines 37 – 60, and Figures 3B and 3C.

29. Regarding Claim 16, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the sample from which the analytes is/are tested for is present in liquid, solid or gaseous form or else in physical intermediate states or combinations thereof. See Col. 3 lines 1 – 26 and Col. 6 lines 44-59.

30. Regarding Claim 17, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that whole blood, capillary blood, umbilical cord blood, arterial or venous whole blood, serum, plasma, urine, feces, tears, saliva, body mucus, dyed solutions, solutions containing solid constituents or high-viscosity liquids are used as the sample. See Col. 1 lines 16-26.

31. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown III et al. in view of Blatt et al. (U.S. PGPub 2005/0249633).

32. Regarding Claim 18, Brown III et al. does not teach that the sample is prepared before, during or afterwards by means of purification, aliquotation, derivatization and/or isolation in order to be applied onto the panel according to the invention.

33. Blatt et al. teach that further manipulations may be required (such as extraction or purification) to prepare a sample suitable for testing for analytes. See [0079].

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the Brown III et al. invention to provide additional preparation/manipulation (such as purification) of the sample for the benefit of making the sample more suitable for testing and speeding up the testing time.

34. Regarding Claim 20, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the immobilized molecules or molecule classes and/or mixtures are visually tested for by means of a detection reaction without additional technical aids. See Col. 3 lines 15-47.

35. Regarding Claim 21, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that technical aids are employed for the read-out and/or evaluation in order to allow a visual evaluation (specifically a conventional spectrophotometer is used), or else the method for instance, densitometric methods, spectroscopic or electrochemical methods are combined with the read-out and/or evaluation according to the invention. See Col. 7 lines 34-54.

36. Regarding Claim 22, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the method is combined with flow-through tests, agglutination tests and/or solid-phase tests and it comprises one, several or many pairs of symbols. See Col. 3 line 36 – Col. 4 line 13 and Col. 9 lines 35-44.

37. Regarding Claim 23, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the method is combined

with the fast lateral-flow test method, and it comprises two, several or many pairs of symbols. See Col. 3 line 50 – Col. 4 line 13.

38. Regarding Claim 24, Brown III et al. teach that the molecules or molecule classes to be tested for are molecules or molecule classes in human medicine, antigen typing, and DNA or RNA detection. See abstract and Col. 1, lines 15-44.

39. Regarding Claim 25, Brown III et al. does teach that the device can be used to improve conventional solid-phase immunoassay techniques for performing colorimetric or other enzyme immunoassay of biological fluids. See Col. 4 lines 38-44. Brown III et al. does not explicitly teach that the method to detect molecules or molecule classes or molecule mixtures, as presented in claim 20, is performed for diagnosis immediately before, during or after a therapeutic measure. However, it would have been obvious to one of ordinary skill in the that the Brown III device would have been used for this purpose since it is well known in the art that conventional solid-phase immunoassays or enzyme immunoassays can be used to diagnose a patient before, during or after a therapeutic measure. See Col. 1 lines 28-58.

40. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown III et al. (U.S. Patent Number 5,160,701) in view of Gao et al. (U.S. PGPub 2006/0134804).

41. Regarding Claim 15, Brown III et al. teach a method to detect molecules or molecule classes or molecule mixtures characterized in that the surfaces are rendered visible as symbols, "-" for negative and "+" for positive, or a circle for negative and a circle with a dot or dots in it for positive. See Col. 11 lines 49 – 67, Col. 17 lines 37 – 60,

and Figures 3B and 3C. Brown III et al. does not explicitly teach symbols consisting of several circles inside each other having one center dot are rendered visible, said dot appearing only in a positive detection case, and whereby each individual circle only becomes visible above a certain concentration value of the analyte or a star with which each of the spokes becomes visible above a certain concentration value and, in the positive case, a predefined spoke appears or the individual spokes detect the presence of several analytes and one spoke appears above a certain concentration value or a combination of these symbols.

42. Gao et al. teach a test device for detecting the presence of an analyte in a liquid sample and indicating to the user the presence or absence of the analyte with recognizable symbols. Gao et al. also teach that the "recognizable symbol" can be a plus sign, a minus sign, a dash, a bar, an "X," or another symbol known in the art or in general as conveying a particular meaning that can be associated with the assay result. Any meaningful symbol can be selected, such as a letter from the Roman alphabet, a number, a mathematical operator, a scientific symbol, or a letter from another language or alphabet system, for example a letter from the Chinese, Japanese, or Arabic alphabets. See [0028]. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention that it would have been obvious to one of ordinary skill in the art to modify the device of Brown III, et al. to provide any meaningful symbol (such as a concentric circle where the center dot only appears in the positive detection case) for the control and detection areas for the benefit of providing easily read and understandable symbols/results to an untrained user while still allowing the symbol to

discern between concentrations of the analyte of interest by only having the center appear when a minimum concentration has been surpassed.

Response to Arguments

36. Applicant's arguments with respect to claims 1-3 and 5-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

38. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER WECKER whose telephone number is

(571)270-1109. The examiner can normally be reached on Monday - Thursday, 9 AM - 6PM and Fridays 9 AM -1 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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